UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE

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| A1 Diabetes & Medical Supply,<br>a Tennessee corporation,<br><br>Plaintiff,<br><br>v.<br><br>Alex M. Azar, II, Secretary of the United States Department of Health and Human Services; and Seema Verma, Administrator for the Centers for Medicare and Medicaid Services,<br><br>Defendants. | CASE NO. |

**VERIFIED COMPLAINT FOR**
**TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION**

Plaintiff A1 Diabetes & Medical Supply, Inc. (hereinafter "Plaintiff" or "A1") is a Medicare Durable Medical Equipment (DME) supplier and the winner of a Medicare Competitive Bidding Contract for mail-order diabetes testing supplies. A1 brings this injunction action against Alex M. Azar, II, Secretary of the United States Department of Health and Human Services (HHS), and Seema Verma, Administrator for the Centers for Medicare and Medicaid Services (CMS), in their official capacities, to request a Temporary Restraining Order and Preliminary Injunction that prohibit the Defendants from improperly recouping alleged overpayments from A1 in direct violation of A1's procedural due process rights, and in support thereof states as follows:

**INTRODUCTION**

1. This is an action for a Temporary Restraining Order and a Preliminary Injunction to prevent Defendants from violating A1's procedural due process rights. A1's procedural due

process rights are jeopardized because the Defendants are unable to comply with the statutorily mandated Medicare appeals process, and specifically the requirement to provide A1 with a timely hearing in front a fair and impartial Administrative Law Judge ("ALJ"). Due to the current and overwhelming backlog of Medicare appeals, providers are currently forced to wait between ***three to five years*** to have their overpayment appeals heard by an ALJ. During this unconscionable period of delay, the Defendants can unilaterally choose to exercise their discretionary recoupment authority and force providers and suppliers into bankruptcy irrespective of whether the provider or supplier would have prevailed on appeal. This is fundamentally unfair and a plain violation of procedural due process.

2. If the Defendants are permitted to proceed with recoupment of the alleged (and disputed) overpayments from A1, A1 with will be forced out of business and to declare bankruptcy – well before A1 has the opportunity to be heard by an ALJ, an opportunity expressly required by federal law.

3. Furthermore, the alleged (and disputed) overpayments were predicated on the flawed results of small audits performed by CMS contractors and then calculated using unreliable statistical sampling and extrapolation methodologies that resulted in exponentially and unjustifiably large alleged overpayment amounts (and in this case astonishingly totaled approximately $7 million). The math and methodology underlying these extrapolations is commonly criticized and subject to expert attack (and has been attacked by A1's statistician expert in the underlying administrative process).

4. Defendants' recoupment of the extraordinary amounts at issue without first providing A1 its statutorily-mandated right to be heard by an ALJ clearly violates A1's procedural due process rights. *See Family Rehab v. Azar*, 886 F.3d 496 (5th Cir. 2018); *see also*

*Accident, Injury & Rehab., PC v. Azar*, No. 4:18-cv-02173-DCC, 2018 U.S. Dist. LEXIS 141629 (D.S.C. Aug. 21, 2018) (issuing TRO preventing CMS from recouping alleged overpayment). The recoupment of approximately $7 million dollars from A1, while a genuine billing dispute remains delayed in the multi-year backlog of hundreds of thousands of appeals pending before HHS's Office of Medicare Hearings and Appeals ("OMHA"), will irreparably harm A1 through the destruction of its business. Accordingly, A1 comes to this Court as a last and only resort.

5. Health care providers and suppliers, including DME suppliers such as A1, furnish services and supplies to Medicare beneficiaries, following which they submit claims for reimbursement to HHS, which processes them through CMS and its contractors. The Medicare Modernization Act of 2003 ("MMA") authorized CMS to conduct post-payment reviews of paid claims through the use of contractors.

6. In a growing number of these post-payment reviews, original (favorable to the provider or supplier) payment determinations are being determined to be erroneous based on the contract reviewers' findings that certain services or supplies were not reasonable or medically necessary based on the requisite criteria.[1] DME suppliers, such as A1, are then informed they must refund to CMS the funds previously reimbursed to them by CMS (known as "overpayments").

7. Under the MMA, providers have the statutory right to then contest unfavorable post-payment findings (and associated alleged overpayments) through a four-level appeals process within HHS, followed by a fifth level of appeal to the judiciary. As explained more fully below, the first level of appeal is known as Redetermination; the second is known as Reconsideration; the third level of appeal is review by an Administrative Law Judge; the fourth

[1] These contractors' findings are often highly subjective and vigorously disputed by the affected providers and suppliers.

level of review is to the Medicare Appeals Council ("Council"); and the fifth level of appeal is (limited) judicial review by a federal district court.

8. The statute prescribes specific timeframes for the provider to file its appeal at each level, as well as specific timeframes in which a decision must be rendered following receipt of the provider's appeal request.

9. Section 935 of the MMA also prevents recoupment of the alleged overpayment (a key issue in this case) until providers have completed the second level of review ("Limitation on Recoupment"). Once this second level of review (i.e., Reconsideration) is completed, CMS has discretionary authority to recoup the alleged overpayment from the provider, despite the fact that the provider disputes the alleged overpayment and has not completed the entire appeals process with respect to the disputed overpayment. Generally speaking, recoupment involves offsetting future payments to the provider up to the full amount of the alleged overpayment, plus interest. In this case, and as explained more fully herein, recoupment would be financially catastrophic for A1 and would result in its bankruptcy, among other things, long before A1 has an opportunity to present its case to an ALJ.

10. The data maintained by OMHA demonstrates that negative Reconsideration decisions are frequently reversed on appeal, and especially when they reach the third level of appeal, where the provider is entitled to have its claim heard by an ALJ. This third level of appeal, which is statutorily required to be completed within 90 days of a request for an ALJ hearing with OMHA, is the first opportunity in the appeals process for a provider's appeal to be heard and reviewed by an adjudicator who is independent from CMS. *See* 42 U.S.C. § 1395ff(d)(1)(A); *see also* 42 C.F.R. §405.1016(a).

11. As a result of increasing audit activity (and associated alleged overpayments), Medicare providers and suppliers have experienced substantial delays in the appeals process, particularly at the ALJ level (where the delay currently takes ***several years*** instead of the statutorily-mandated 90 days), which violates the providers' procedural due process rights because they are unable to obtain a timely ALJ hearing in order to challenge the alleged overpayment before CMS exercises its discretionary authority to recoup the alleged (and disputed) overpayment amount in the interim.

12. Not only does this extraordinary delay violate the health care providers' and suppliers' procedural due process rights, it also violates the governing federal statute, which expressly requires the ALJ to hold a hearing and render a decision within 90 days of an appeal being filed with OMHA. *See* 42 U.S.C. § 1395ff(d)(1)(A). In practice, providers are currently forced to wait between ***three to five years*** to have their appeals heard by an ALJ. In 2014, OMHA reported an average 28-week (i.e., 196 days) delay in having ALJ appeals simply *docketed*, much less actually holding an ALJ hearing or rendering a decision. In December 2017, OMHA reported that the average wait time for an ALJ hearing was 1000 days. In other words, at present, a provider cannot even obtain a timely ALJ assignment, much less a timely hearing or decision.[2]

13. When the excessive delays at the ALJ level are considered in conjunction with existing delays in other steps of the appeals process, the consequences are troubling: providers

[2] *See* FY 2018 President's Budget for the Department of Health and Human Services, Office of the Secretary, Office of Medicare Hearings and Appeals, at p. 91, *available at* https://www.hhs.gov/sites/default/files/Consolidated%20BIB_ONLINE_remediated.pdf, which is attached as Exhibit 1; Bombalier, Lanchi, *et al.*, Arnall Golden Gregory, LLP, "CMS Announces Low Volume Appeal Settlement Options for Providers Mired in ALJ Backlog" (Jan. 24, 2018), *available at* https://www.agg.com/CMS-Announces-Low-Volume-Appeal-Settlement-Option-for-Providers-Mired-in-ALJ-Backlog-01-24-2018/, which is attached as Exhibit 2.

and suppliers will likely wait five years, or even longer, to have their appeals proceed through an administrative process that, by federal law, should be completed by no later than one calendar year.

14. Defendants possess only a discretionary authority to recoup overpayments after the second level of appeal – a discretionary authority that must be balanced against the mandatory requirement to provide an ALJ hearing and decision within 90 days of a request. It is thus fundamentally unfair – and a clear denial of A1's right to due process – that CMS may recoup over $7 million from A1 and bankrupt its business years before A1 receives its right to be heard by an unbiased ALJ as required by federal law.

15. The extraordinary amount of money that CMS will recoup from A1 combined with the excessive backlog of appeals before OMHA will effectively strip A1 of the administrative appeals due process to which it is entitled by statute. Thus, without intervention by this Court, this statutorily mandated appeals process becomes entirely moot.

16. Critical here, A1 is not asking this Court to assume the power of the ALJ to decide any issue with respect to the underlying overpayment dispute. A1 simply requests that this Court maintain the status quo pending A1's receipt of an ALJ hearing and decision. Without such temporary relief, A1 will be irreparably harmed before having any meaningful opportunity for the administrative and judicial review to which it is statutorily entitled.

17. A1 therefore seeks a Temporary Restraining Order and a Preliminary Injunction preventing the Defendants from recouping the approximately $7 million in alleged overpayments (overpayments A1 disputes) until A1 has been afforded a hearing before an impartial and unbiased ALJ.

**JURISDICTION AND VENUE**

18. This action arises under the Social Security Act, 42 U.S.C. § 301 *et seq.*, the Medicare Act, 42 U.S.C. § 1395 *et seq.*, as well as the Fifth and Fourteenth Amendments to the United States Constitution.

19. This Court has jurisdiction over this action pursuant to 42 U.S.C. § 405(g) and 42 U.S.C. § 1395ff(b)(1)(A). A1 is also entitled to the judicial relief it seeks pursuant to the Administrative Procedures Act ("APA"), 5 U.S.C. § 705.

20. A1 is currently challenging the overpayments at issue through the applicable administrative process; however, ALJs do not have the authority to issue an injunction to stay recoupment by CMS and maintain the status quo until a final decision has been issued by an ALJ. Accordingly, A1 lacks an adequate administrative remedy through which it can obtain the relief it seeks in this suit – the deferment of recoupment until after A1 has had the opportunity to appear before a fair and impartial ALJ.

21. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 405 under the "waiver" exception to the channeling requirement that administrative remedies be exhausted. Exhaustion of administrative remedies under the Medicare Act is waived when a plaintiff asserts a collateral challenge to its substantive claims which cannot be remedied after exhaustion of administrative review. A1 meets both such requirements and is thus not required to exhaust its administrative remedies prior to requesting the relief sought herein. *See Family Rehab v. Azar*, 886 F.3d 496 (5th Cir. 2018); *see generally Accident, Injury & Rehab., PC v. Azar*, No. 4:18-cv-02173-DCC, 2018 U.S. Dist. LEXIS 141629 (D.S.C. Aug. 21, 2018) (issuing TRO preventing CMS from recouping money from Plaintiff in factually similar circumstances); *D&G Holdings LLC v. Burwell, et al.*, No. 15-2624 (W.D. La. February 17, 2016), DE #62, "Order Granting

Preliminary Injunction" (issuing PI preventing CMS from recouping money from Plaintiff based on alleged overpayment in factually similar circumstances), which is attached as Exhibit 3.

22. A1's request for injunctive relief based on the claims asserted herein is collateral to its substantive claims in the billing dispute and appeal. A1 does not request that the Court resolve or make any factual determination regarding the merits of the underlying billing dispute. Instead, A1 requests the Court preclude Defendants from engaging in recoupment based on the preliminary and disputed determinations of its own contractors until A1 has been afforded its right to a ruling from an impartial and unbiased ALJ.

23. Irreparable injury to A1 cannot be remedied after the exhaustion of administrative review. A1 has appealed and requested hearings before an ALJ to address its substantive claims. Due to the amounts that Defendants may recoup and the extraordinary delay of three to five years before any ALJ hearing can be held, recoupment will force A1 out of business long before it has the opportunity to appear before an unbiased ALJ.

24. Venue lies in this judicial district pursuant to 42 U.S.C. § 405(g), 28 U.S.C. § 1391(b) and (e), and 5 U.S.C. § 703.

## PARTIES

25. Plaintiff A1 Diabetes & Medical Supply, Inc., is a Medicare DME supplier servicing Medicare and other patients across the country. As a winner of Medicare's 2013 Competitive Bidding Contract for mail order diabetes supplies, A1 plays a critical role in ensuring that Medicare beneficiaries receive medically necessary diabetic testing supplies, among other things. A1 is located at 1785 Nonconnah Blvd., Ste. 110, Memphis, TN 38132.

26. Defendant Alex Azar, II, is the Secretary of the Department of Health and Human Services (the "Secretary"), the federal agency charged with overseeing the operation of the Medicare program. Secretary Azar is sued in his official capacity only.

27. Defendant Seema Verma, is the Administrator of CMS and is sued in her official capacity only.

## REGULATORY BACKGROUND

### A. Medicare

28. Medicare is a government health insurance program administered by HHS through CMS that was established by Title XVIII of the Social Security Act. *See* 42 U.S.C. §§ 1395 *et seq*. The health insurance provided to beneficiaries of the Medicare program is paid in whole or in part by the United States. Medicare was enacted to provide payment for medical services, inpatient drugs, DME, and other related health items for individuals 65 and over, as well as for certain disabled or seriously ill individuals. A1 qualifies as a provider of services under Title XVIII, commonly known as the Medicare Act.

29. The Medicare program is divided into four parts, A through D. Part B, the supplemental medical insurance program, pays for various "medical and other health services" not covered by Part A, including physician services, hospital outpatient services, and DME. 42 U.S.C. § 1395k(a); §§ 13985j–1395w-4j. To be covered by Medicare Part B, medical services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." *Id.* § 1395y(a). Part B is the only part relevant to this proceeding.

30. The Secretary has implemented the Medicare program through guidance published in various manuals, such as the Medicare Benefits Policy Manual. These manual

provisions are not promulgated in accordance with the notice and comment provisions of the APA, and therefore are not binding rules.

**B. Medicare Administrative Contractors and Zone Program Integrity Contractors**

31. Pursuant to Section 911 of the Medicare Prescription Drug Improvement and Modernization Act of 2003, Medicare Part A and Part B carriers were replaced with Medicare Administrative Contractors ("MACs"). These multi-state regional contractors are responsible for administering both Medicare Part A and Part B claims, as well as serve as the primary operational contact between the Medicare Fee-For-Service program and the health care providers and suppliers enrolled in the Medicare program. CMS reimburses Medicare providers and suppliers for covered claims with payments from the MACs. *See* 42 U.S.C. § 1395kk-1(a)(3).

32. Medicare DME suppliers such as A1 submit claims for reimbursement to the MAC appointed to its geographical area. *See* 42 U.S.C. § 1395ff(a)(2)(A). For many years, A1 serviced Medicare beneficiaries nationwide and therefore submitted claims to MACs located in several geographic locations, including Noridian Healthcare Solutions ("Noridian") and CGS Administrators, LLC ("CGS"), among others.

33. Some claims that are initially paid by MACs are then subjected to an additional level of oversight through a process known as "post-payment review." During post-payment reviews, third-party contractors audit MAC payment decisions and, frequently, determine that the MAC's initial decision to pay a claim was erroneous. Post-payment reviews have placed a significant burden on the appeals process, including the audits performed by one type of such contractor, known as a Zone Program Integrity Contractor ("ZPIC").

34. The primary role of ZPICs is to identify cases of suspected fraud, investigate them, and take action to ensure any inappropriate Medicare payments (i.e., overpayments) are

recouped.[3] However, it is commonly accepted in the health care industry that ZPICs have engaged in overly aggressive, outcome determinative audit activity designed to identify what the ZPICs (erroneously) allege to be overpayments, which the ZPICs then forward to the MACs for recoupment.

35. Even worse, in most cases, ZPICs often employ unreliable "statistical sampling" to calculate and project (i.e., extrapolate) the amount of the alleged total overpayment (and did so in each of the alleged overpayments at issue for A1). This extrapolation process often results in an extraordinarily large overpayment amount derived from the findings of an audit performed on a very small number of claims, typically numbering less than fifty. The math and methodology underlying these extrapolations is commonly criticized and subject to expert attack (and has been attacked by A1's statistician expert in the underlying administrative process).

36. If a ZPIC's extrapolation methodology is deemed unreliable, this has the effect of exponentially decreasing any alleged overpayment, which would likewise be the case for A1. Experience dictates that the ALJ level of appeal is where the ZPICs' extrapolation methodology is properly tested (and potentially deemed unreliable), such as through the use of expert witnesses, thus underscoring the vital importance of the ALJ level of appeal to A1.[4]

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[3] ZPICs have the authority to identify (but not collect) alleged overpayments. Instead, ZPIC-identified overpayments must be referred by the ZPICs back to the appropriate MACs so that the MACs can then issue formal demand letters and initiate recoupment. The formal demand letters trigger the statutory appeals process and associated deadlines.

[4] A1 is challenging the statistical sampling methodology for all of the alleged overpayments in the underlying administrative appeals at issue and has retained a nationally-recognized statistician as an expert witness, who has provided reports demonstrating the deficiencies and unreliability in the various ZPICs' extrapolation methodology.

37. ZPICs are paid on a contractual basis, with the opportunity to earn all or part of an allotted "award fee" based on CMS's annual evaluation of the ZPIC's performance.[5]

38. ZPIC claim denials are frequently overturned on appeal. According to data provided to the American Hospital Association ("AHA"), through the first quarter of 2013, hospitals reported that when they appealed a post-payment auditor's denials, including up to an ALJ, the denials were overturned 70% of the time.[6]

39. In an April 2015, United States Senate hearing before the Committee on Finance, the Honorable Senator Orrin Hatch testified that over 60% of claims are overturned in favor of the providers when heard by an ALJ.[7]

**C. The Medicare Appeals Process**

40. Pursuant to the Social Security Act, aggrieved providers can engage in a four-level administrative appeal process, followed by judicial review. *See Am. Hosp. Assoc. v. Burwell*, 812 F.3d 183, 185 (D.C. Cir. 2016) (citation omitted).

41. In the first level of review, the alleged overpayment and associated claims at issue are presented to the MAC for Redetermination. *See* 42 U.S.C. § 1395ff(a)(3)(A). The MAC is

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[5] *See* United States Government Accountability Office's Report to Congressional Requesters, "Medicare Program Integrity: Contractors Reported Generating Savings, but CMS Could Improve Its Oversight," GAO-14-11 (Oct. 2013), *available at* https://www.gao.gov/assets/660/658565.pdf, which is attached as Exhibit 4.

[6] *See* AHA, Exploring the Impact of the RAC Program on Hospitals Nationwide, at 55 (Jun. 1, 2013), *available at* https://www.aha.org/system/files/content/16/15q4ractracresults.pdf, which is attached as Exhibit 5.

[7] *See* Opening Statement of the Honorable Orrin Hatch at April 28, 2015 Hearing before the Finance Committee of the United States Senate, Creating A More Efficient and Level Playing Field: Audit and Appeal Issues in Medicare, *available at* https://www.finance.senate.gov/hearings/creating-a-more-efficient-and-level-playing-field-audit-and-appeals-issues-in-medicare, which is attached as Exhibit 6.

statutorily required to issue its decision on Redetermination within 60 days from its receipt of the request for Redetermination. *Id*. at § 1395ff(a)(3)(C)(ii).

42. At the second level of review, if dissatisfied with the result at the MAC's redetermination, a provider can seek Reconsideration form a Qualified Independent Contractor ("QIC"), which includes an independent record review by a panel of physicians or other healthcare professionals. The appeal must be filed within 180 days from the date the party received the Redetermination decision. The QIC is statutorily required to issues its decision on reconsideration within 60 days of its receipt of the reconsideration request. *Id*. at § 1395ff(c).

43. Both of the Redetermination and Reconsideration review processes are overseen by CMS. *See Burwell*, 812 F.3d at 185.

44. At the third level of review, a dissatisfied party may appeal within 60 days of its receipt of the QIC Reconsideration decision and request a hearing before an ALJ at OMHA. Notably, this is the first step of the appeals process that is independent from CMS. "This stage of the process is overseen by the Office of Medicare Hearings and Appeals [], which houses ALJs and their support staff, and which is funded by a separate appropriation." *Id*. at 185-86 (citations omitted).

45. The ALJ is statutorily required to hold a hearing on the allegedly overpaid claims ***and*** render a decision within 90 days of receipt of the request for an ALJ hearing. *See* 42 U.S.C. § 1395ff(d)(1)(A). When providers have been granted an ALJ hearing as required by law, it is the level of the appeals process at which providers have historically been able to obtain relief from adverse ZPIC determinations at levels reportedly as high as 60% to 72%.

46. Providers may avoid recoupment during the first two levels of review by requesting appeals within a specified timeframe. *See* Section 935 of the MMA. This is referred

to as a Limitation on Recoupments. *See id.* The Limitation on Recoupments is not available following completion of the second level of review – in other words, while the appeal is pending at the ALJ or any subsequent stage – and CMS has the discretionary authority to recoup the overpayment. This discretionary authority to recoup is statutorily balanced by the mandated requirement that the ALJ's hearing and decision occur within 90 days of receipt of the request for an ALJ hearing.

47. If a party is still dissatisfied after the ALJ issues its decision, it may appeal the decision within 60 days to the Medicare Appeals Council ("Council") within the HHS Departmental Appeals Board ("DAB"). The Council is independent of both CMS and OMHA. The Council must render a decision or remand the case to the ALJ within 90 days from the date of the request for review. Generally speaking, only the DAB decision qualifies as the "final" decision of the Secretary for judicial purposes. *See* 42 U.S.C. § 1395ff(f)(2)(A)(iv).

48. Finally, a party may request judicial review in a federal district court within 60 days of the date of receipt of the DAB's decision.

**D. Medicare Appeals Backlog and Resulting Delays in Adjudication Times**

49. Despite the statutorily-mandated time periods governing the appeals process, in practice, it takes an aggrieved appellant much longer to fully pursue its claim through the Medicare appeals process due to the colossal backlog of Medicare appeals.

50. An exponential increase in appeals has caused this growing delay in the Medicare appeals process. In fact, the number of Medicare appeals grew from 35,831 appeals in Fiscal Year ("FY") 2009 to over 594,000 in FY 2017 – an almost twentyfold increase. *See Am. Hosp. Assoc. v. Sylvia M. Burwell*, Case No. 1:14-cv-00851 (D.C. Dist. Dec. 18, 2014), at DE# 58-1, Decl. of Jennifer Moughalian ("Moughalian Decl."), ¶ 7, which is attached as Exhibit 7.

51. OMHA predicts that the number of pending appeals will rise to 972,591 – almost one million – by the end of FY 2021 (September 30, 2021). *Id*. at ¶ 9.

52. The backlog is so severe that the FY 2018 President's Budget allots $1.3 billion "to address the pending backlog[.]" *See* FY 2018 President's Budget for the Department of Health and Human Services, at p. 7, attached as Exhibit 1. Despite this allotment, OMHA still predicts that the number of pending appeals will be over 500,000 through FY 2019, and under the best of circumstances, the number of pending appeals will have only dropped to 375,674 by the end of FY 2021. *See* Moughalian Decl. ¶¶ 12, 13.

53. By OMHA's own admission, the ALJs have simply been unable to keep up with the increasing volume of Medicare appeals and requests for ALJ hearings. As of OMHA's September 1, 2017 status report, OMHA has received 167,899 new appeals for adjudication in 2017, but has only been able to adjudicate 76,000 of its total 595,000 outstanding appeals. *Id.* The rate at which the ALJs can adjudicate these appeals is far below the rate at which new appeals are being filed, resulting in a long and ever-growing backlog.

54. As of February 2014, the average wait time for a provider's case to even be assigned to an ALJ docket was twenty-eight (28) weeks.[8] As of 2017, the average wait time for

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[8] *See* OMHA Medicare Appellant Forum Presentation (Feb. 12, 2014), *available at* https://www.hhs.gov/sites/default/files/omha/OMHA%20Medicare%20Appellant%20Forum/omha_medicare appellant_forum_presentations.pdf, which is attached as Exhibit 8.

a provider's case to be heard by an ALJ was over 1000 days.[9] As of 2018, the average wait time for a provider's case to be heard by an ALJ is over 1,200 days.[10]

55. Based on the growing number of appeals, the situation is only worsening for providers. The predicted wait times to obtain an ALJ hearing once a case is assigned to an ALJ means that providers who lodge new appeals from the QIC to the ALJ, such as A1, can realistically expect to wait three to five years – and perhaps longer – to even obtain an ALJ assignment, participate in a substantive hearing, and receive a decision.

**<u>THE UNDERLYING MEDICARE APPEALS</u>**

56. In 2017, A1 was subjected to a series of post-payment audits by multiple ZPICs/UPICs.[11] Each of the audits (almost predictably) resulted in an alleged overpayment, each employed unreliable statistical sampling methodologies, and altogether totaled approximately $7 million in alleged overpayments. Each of alleged overpayments was timely appealed through both the Redetermination and Reconsideration levels, and A1 has recently began receiving the Reconsideration Decisions related to those appeals, thus triggering A1's right to demand an ALJ hearing, which it has done. The Reconsideration Decisions received to date (alleging approximately $5 million in overpayments that can be recouped) are specifically discussed below. The remaining reconsideration decisions are due and expected imminently, but

[9] *See* FY 2018 President's Budget for the Department of Health and Human Services, Office of the Secretary, Office of Medicare Hearings and Appeals, at p. 91, *available at* https://www.hhs.gov/sites/default/files/Consolidated%20BIB_ONLINE_remediated.pdf, which is attached as Exhibit 1.

[10] *See* FY 2019 President's Budget for HHS, Office of the Secretary, Office of Medicare Hearings and Appeals, at p. 119, *available at* https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf, which is attached as Exhibit 9.

[11] UPICs are a new type of reviewing contractor known as Unified Program Integrity Contractors and for purposes of this complaint are the functional equivalent of ZPICs.

there is no functional distinction between $5 million and $7 million in terms of recoupment's catastrophic impact on A1.[12]

**A. Noridian Overpayment ($560,452.00)**

57. In 2017, a ZPIC named AdvanceMed, initiated a post-payment review of an alleged statistically valid random sample of A1 claims with dates of service December 5, 2012, through December 30, 2016. AdvanceMed reviewed 34 claims and concluded that A1 owed an overpayment amount of **$7,315.82** based on an alleged 56% error rate. AdvanceMed then extrapolated the overpayment, in an effort to improperly inflate the actual overpayment amount, using invalid and unproven methodologies. As a result of the extrapolation, the overpayment was increased to **$560,452.00**.

58. On March 12, 2018, Noridian (the MAC) issued an Overpayment Demand letter in the amount of $560,452.00. A1 timely requested a Redetermination to Noridian, challenging in detail the overpayment determinations of the claims in the underlying sample. On April 23, 2018, Noridian issued a partially favorable Redetermination decision, as well as an unfavorable decision.

59. A1 timely requested a Reconsideration to C2C Innovative Solutions, Inc., and the C2C issued its unfavorable decision on August 9, 2018.

60. On August 15, 2018, A1 timely submitted a request for an ALJ hearing to challenge the overpayment determinations of the claims in the underlying sample, as well as to challenge the statistical sample and extrapolation methodology.

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[12] Final Reconsideration decisions for the remaining ZPIC-identified alleged overpayments have not been received but are due and expected imminently, and this complaint will be amended accordingly to reflect their receipt. To date, A1 has received three final Reconsideration decisions (and one notice of final Reconsideration decision) totaling approximately $5 million in alleged overpayments, as well as written notice of intent to initiate recoupment from two MACs with respect to approximately $3.7 million, which would be financially catastrophic for A1.

61. On August 21, 2018, A1 received notice from Noridian (dated August 13, 2018) that Noridian intends to initiate recoupment within 30 days of the date of the reconsideration letter (i.e., within 30 days of August 9, 2018). A copy of this notice is attached as Exhibit 10. This notice also invited A1 to submit a rebuttal explaining why recoupment should not be initiated, which A1 submitted. As of the date of this filing, A1 has not received any response to this rebuttal.

**B. <u>CGS Overpayment ($461,485.00)</u>**

62. In 2017, a ZPIC named SafeGuard Services, LLC, initiated a post-payment review of an alleged statistically valid random sample of A1 claims with dates of service July 22, 2014, through December 22, 2016. SGS reviewed 35 claims and concluded that A1 owed an overpayment amount of **$21,012.86** based on an alleged 100% error rate. SGS then extrapolated the overpayment, in an effort to improperly inflate the actual overpayment amount, using invalid and unproven methodologies. As a result of the extrapolation, the overpayment was increased to **$461,485.00**.

63. On January 31, 2018, CGS issued an Overpayment Demand letter in the amount of $461,485.00. A1 timely requested a Redetermination to CGS, challenging in detail the overpayment determinations of the claims in the underlying sample. On April 20, 2018, CGS issued an unfavorable Redetermination decision.

64. A1 timely requested a Reconsideration to C2C Innovative Solutions, Inc., and the C2C issued its unfavorable decision on August 1, 2018.

65. On August 9, 2018, A1 timely submitted a request for an ALJ hearing to challenge the overpayment determinations of the claims in the underlying sample, as well as to challenge the statistical sample and extrapolation methodology.

**C. <u>CGS Overpayment ($982,920.59)</u>**

66. In 2017, a ZPIC named Health Integrity, LLC, initiated a post-payment review of an alleged statistically valid random sample of A1 claims with dates of service July 19, 2013, through June 22, 2016. Health Integrity reviewed 68 claims and concluded that A1 owed an overpayment amount of **$18,204.90** based on an alleged 67.6% error rate. Health Integrity then extrapolated the overpayment, in an effort to improperly inflate the actual overpayment amount, using invalid and unproven methodologies. As a result of the extrapolation, the overpayment was increased to **$982,920.59**.

67. On January 31, 2018, CGS issued an Overpayment Demand letter in the amount of $982,920.59. A1 timely requested a Redetermination to CGS, challenging in detail the overpayment determinations of the claims in the underlying sample. On April 23, 2018, CGS issued a partially favorable Redetermination decision.

68. A1 timely requested a Reconsideration to C2C Innovative Solutions, Inc., and the C2C issued its unfavorable decision on August 17, 2018.

69. On August 27, 2018, A1 timely submitted a request for an ALJ hearing to challenge the overpayment determinations of the claims in the underlying sample, as well as to challenge the statistical sample and extrapolation methodology.

**<u>CGS Overpayment ($3,134,871.00)</u>**

70. In 2017, a ZPIC named AdvanceMed, initiated a post-payment review of an alleged statistically valid random sample of A1 claims with dates of service January 7, 2013, through October 31, 2016. AdvanceMed reviewed 63 claims and concluded that A1 owed an overpayment amount of **$21,170.75** based on an alleged 81% error rate. AdvanceMed then extrapolated the overpayment, in an effort to improperly inflate the actual overpayment amount,

using invalid and unproven methodologies. As a result of the extrapolation, the overpayment was increased to **$3,134,871**.

71. On January 31, 2018, CGS (the MAC) issued an Overpayment Demand letter in the amount of $3,134,871.35. A1 timely requested a Redetermination to CGS, challenging in detail the overpayment determinations of the claims in the underlying sample. On April 24, 2018, CGS issued an unfavorable Redetermination decision.

72. A1 timely requested a Reconsideration to C2C Innovative Solutions, Inc. On August 28, 2018, A1 received notification from CGS (dated August 22, 2018) that the C2C had apparently issued an unfavorable Reconsideration decision on August 10, 2018, and that CGS intends to initiate recoupment within 30 days of the date of the notification letter (i.e., within 30 days of August 22, 2018). A copy of this notification is attached as Exhibit 11. As of the date of the filing of this Complaint, A1 has not received a copy of the C2C's actual Reconsideration Decision. This notice also invited A1 to submit a rebuttal explaining why recoupment should not be initiated, which A1 submitted. As of the date of this filing, A1 has not received any response to this rebuttal.

73. In an abundance of caution, on August 29, 2018, A1 timely submitted a request for an ALJ hearing to challenge the overpayment determinations of the claims in the underlying sample, as well as to challenge the statistical sample and extrapolation methodology.

## CLAIM FOR RELIEF

74. Medicare can begin recouping the alleged overpayment(s) at any time and at least two MACs have already threatened in writing to imminently do so with respect to approximately $3.7 million of alleged overpayments. A1 cannot wait for recoupment to initiate before seeking relief from this Court because recoupment will force A1 to cease operations and declare

bankruptcy in a matter of weeks. A1 is already under intense financial pressure due to, among other things, significantly declining reimbursement rates, razor thin profit margins on diabetic testing supplies (A1's principal Medicare DME line of business), and the significant resources A1 has expended and continues to expend vigorously fighting the alleged overpayments.

75. Medicare receivables constitute approximately 90% of A1's revenues. As a result, A1 will lose an estimated 90% of its revenue once recoupment is initiated. Recoupment will force A1 to completely cease operations within weeks.

76. As of the date of this pleading, A1 serves approximately 40,000 Medicare patients across the country. Once recoupment is initiated, A1 will have to effectively cease providing its services, and many of these patients will experience service disruption with respect to their medically necessary DME, such as diabetic testing supplies.

77. Once CMS initiates recoupment, A1 will initiate bankruptcy proceedings.

78. A1 is not financially able to survive recoupment for the three to five years, or more, that it will take to finally receive an ALJ hearing and decision.

79. In light of the fact that approximately 90% of its revenue stream is derived from Medicare services, and in conjunction with the financial stress A1 is already battling, A1 is unable to survive recoupment at all.

80. Under these circumstances, including the extraordinary backlog of appeals at the ALJ level, the administrative appeal process provided by 42 C.F.R. § 405.1000, *et seq*., does not afford an adequate remedy at law because recoupment would force A1 to close long before it could ever receive an ALJ hearing – much less proceed to the remaining two levels of the appeals process. For this reason, A1 seeks only to preserve the status quo through injunctive relief pending its receipt of an ALJ hearing and decision as statutorily mandated.

81. If recoupment is allowed to initiate, A1 will go bankrupt and be unable to recover from the irreparable harm it has suffered years before it could receive its first opportunity at meaningful review by an impartial and unbiased ALJ. Without temporary relief, A1 will not be able to recover, will permanently close its doors, and any relief it could have received from an ALJ will be moot.

82. The requested relief will not adversely affect the Government or any public interest – in fact, an injunction would instead serve the public interest. Defendants have not alleged any quality of care issues for A1's patients, and thus no possible public interest is served by forcing patients to suffer this disruption in care while the administrative appeals process plays out over many years. Moreover, the Medicare funds that Defendants will withhold from A1 will still need to be spent for each of these patients being forced to seek alternative care. The only harm resulting from the recoupment is to A1, its patients, and its employees.

83. Indeed, Defendants are statutorily mandated to provide A1 with an ALJ hearing and decision within 90 days of A1 making a request. Conversely, the Defendants' ability to recoup is a discretionary authority and one that must be balanced against the mandatory requirement to provide a hearing and decision within 90 days of a request. Because Defendants are required to provide A1 with a timely hearing, staying recoupment until such time as Defendants have provided A1 with its mandated right to a hearing provides the appropriate balance between the provider's due process rights and the Government's discretionary authority. The deprivation of Medicare payments to A1 and accordingly, the demise of A1's business, without a timely ALJ hearing as mandated by statute does not provide sufficient due process as required by the U.S. Supreme Court in *Mathews v. Eldridge*, 424 U.S. 319 (1976).

84. A1's Medicare payments, its legitimate expectations for receipt of Medicare payments for DME supplies provided to patients, its interest in engaging in the DME business and maintaining the goodwill associated therewith, and its statutory right to a timely ALJ hearing, constitute valuable property and liberty rights and interests within the meaning and protection of the Medicare Modernization Act of 2003 and the Due Process Clause of the Fifth Amendment to the United States Constitution. A1 is likely, if not certain, to prevail on its underlying procedural due process claim.

85. Moreover, there is a high risk of an erroneous deprivation of A1's due process rights in light of the consistent rate of reversal at the ALJ level of appeal and A1's likelihood of success on the merits of its substantive claims. The extraordinary amount of the recoupment, combined with the excessive backlog of claims at the ALJ level, will force A1 out of business years before A1 receives an ALJ hearing, effectively denying A1 the process to which it is entitled by statute. Defendants' recoupment of approximately $7 million without providing A1 the opportunity to be heard by an ALJ, as required by the applicable statute, is ultra vires and violates A1's due process rights.

86. A1 seeks only to preserve the status quo pending its receipt of an ALJ hearing as statutorily mandated. A1 therefore seeks a Temporary Restraining Order and Preliminary Injunction preventing the Defendants from recouping from A1's Medicare payments prior to a hearing and decision from an unbiased and impartial ALJ on the merits of the billing dispute.

## COUNT ONE
## PROCEDURAL DUE PROCESS

87. The allegations contained in paragraphs 1 through 84 of this Complaint are incorporated by reference as if fully set out herein.

88. Defendants are statutorily required to provide A1 with an ALJ hearing and decision within 90 days of its request. *See* 42 U.S.C. §1395ff(d)(1)(A); 42 C.F.R. §405.1016(a). Defendants have acknowledged they will not be able to meet this requirement for three to five years.

89. Defendants' recoupment of the alleged overpayment will cause A1 devastating harm to its business and will force A1 out of business well before any hearing before an ALJ is held. Any post-hearing monetary relief that A1 could gain from an ALJ hearing would be moot, as A1 would no longer exist at the time such relief was granted. Without the temporary relief requested herein, A1 will suffer the fatal consequence of permanent closure.

90. Defendants cannot demonstrate any harm to the Government as a result of the temporary relief requested by A1. Yet the harm suffered by A1 if the requested relief is not granted is irreparable. A1 merely requests for the status quo to be maintained until Defendants have satisfied their statutory obligation to grant A1 a fair and impartial hearing before an ALJ. The balance of the harms clearly weighs in favor of A1.

91. Defendants are threatening to deprive A1 of its property and liberty interests in or associated with its Medicare payments, goodwill, and a timely and fair hearing without due process of law, in violation of the Medicare Modernization Act of 2003 and the Fifth Amendment of the United States Constitution and other applicable law. The issuance of temporary injunctive relief prohibiting such recoupment until such due process is provided will not harm the Defendants and is in the public interest.

**COUNT TWO**
**ULTRA VIRES**

92. The allegations contained in paragraphs 1 through 84 of this Complaint are incorporated by reference as if fully set out herein.

93. Defendants are required to provide A1 with an ALJ hearing and decision within 90 days of its request. *See* 42 U.S.C. § 1395ff(d)(1)(A); 42 C.F.R. § 405.1016(a).

94. Defendants are threatening to recoup from A1's Medicare payments even though they cannot and will not provide an ALJ hearing in the statutorily required time frame. The Court should enjoin Defendants from engaging in such ultra vires actions against A1, which actions are contrary to the limitations on the Defendants' authority as set forth in Title XVIII of the Social Security Act.

## COUNT THREE
## PRESERVATION OF RIGHTS UNDER SECTION 704 OF THE APA

95. The allegations contained in paragraphs 1 through 84 of this Complaint are incorporated by reference as if fully set out herein.

96. In relevant part, the Administrative Procedure Act provides that "[o]n such conditions as may be required and to the extent necessary to prevent irreparable injury, the reviewing court, including the court to which a case may be taken on appeal from or on application for certiorari or other writ to a reviewing court, may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings." 5 U.S.C. § 705.

97. This Court is a "reviewing court" and a "court to which a case may be taken on appeal." *See* 42 U.S.C. §§ 405(g), 1395ii.

98. As outlined above, A1 has meritorious challenges to the billing dispute underlying the threatened recoupment from Medicare payments, and will vigorously assert its arguments during the administrative appeals process that has already been initiated as promptly and expeditiously as the ALJ can accommodate. In the meantime, if immediate injunctive relief is not granted "to preserve the status or rights pending conclusion of the review proceedings,"

however, A1's right to administrative review in an ALJ hearing will be eliminated by the inability of A1 to remain in existence due to the crippling effect of the threatened Medicare recoupment.

99. Accordingly, pursuant to 5 U.S.C. §705, issuance of the injunctive relief is necessary and appropriate to prevent irreparable injury and to preserve the Court's jurisdiction to review the result of the administrative appeals process related to the underlying billing dispute.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff prays that the Court grant it the following relief:

(a) That Plaintiff, pursuant to Federal Rule of Civil Procedure 65, be granted a Temporary Restraining Order, Preliminary Injunction, and any other injunctive relief against Defendants necessary to preserve the status quo as more fully described herein; and

(b) That Plaintiff be granted such other legal or equitable relief as the nature of their claims may require.

**THIS IS PLAINTIFF'S FIRST REQUEST FOR EXTRAORDINARY RELIEF.**

Respectfully submitted,

s/ Jonathan E. Nelson
John S. Golwen (B.P.R. #14324)
Jonathan E. Nelson (B.P.R. #28029)
BASS, BERRY & SIMS, PLC
100 Peabody Place, Suite 1300
Memphis, Tennessee 38103-3672
Telephone: (901) 543-5900
Email: jgolwen@bassberry.com
jenelson@bassberry.com
and

Robert N. Nicholson (Florida Bar No. 933996; *pro hac vice* application forthcoming)
Parker D. Eastin (Florida Bar No. 48044; *pro hac vice* application forthcoming)

Erin M. Ferber (Florida Bar No. 68216; *pro hac vice* application forthcoming)
NICHOLSON & EASTIN, LLP
707 N.E. Third Avenue, Suite 301
Fort Lauderdale, Florida 33304
Telephone: (954) 634-4400
Facsimile: (954) 634-4418
Email: Robert@NicholsonEastin.com
Parker@NicholsonEastin.com
Erin@NicholsonEastin.com

Attorneys for Plaintiff A1 Diabetes & Medical Supply

**VERIFICATION**

I declare under penalty of perjury under the laws of the United States of America and the State of Tennessee that the foregoing facts are true and correct.

John Pereira, CEO of A1 Diabetes & Medical Supply, Inc.

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